

REMARKS

Restriction and Election of Species Requirements

The Examiner has required restriction between, Claims 1 – 28 and 43 (Group I), drawn to a composition comprising a β -strand forming peptide having β -strand forming amino acid residues and amino acids that undergo N α -modification; Claims 29, 31 and 36 (Group II), drawn to a method of inhibiting aggregation of target β -strands or proteins using composition of Group I; Claims 30, 32, 34 and 37 – 38 (Group III), drawn to a method of making a medication comprising the composition of Group I; Claims 33 (Group IV), drawn to a method of promoting refolding of denatured or aggregated protein using the composition of Group I; Claim 35 and 44 – 45 (Group V), drawn to a method of treating or diagnosing a disease using composition of Group I; Claims 39 (Group VI), drawn to a method of indicating the presence of diagnosing a β -structure using composition of Group I; Claim 40 (Group VII), drawn to a method of preparing an agent comprising the composition of Group I; Claim 41 (Group VIII), drawn to a method of performing a protein denaturation chromatography using composition of Group I; and Claim 42 (Group IX), drawn to a combinational library comprising the composition of Group I. In addition, if Group V is elected, Applicant is required to elect one disease state from Claim 45.

Applicant hereby elects Claims 1 – 28 and 43 (Group I), drawn to a composition comprising a β -strand forming peptide having β -strand forming amino acid residues and amino acids that undergo N α -modification, for further prosecution, **with traverse**.

The Examiner has indicated that the invention listed as Groups I – IV do not related to a single general invention concept under PCT Rule 13.1 because they lack the same or corresponding technical features. More specifically, the instant Claim 1 has been allegedly deemed obvious over Quibell M. et al. (J. Chem. Soc. Perkin. Trans (1995) 1, 2019-2024), hereinafter Quibell.

Applicant traverses the restriction requirement and respectfully submits that Quibell reference does not render Claim 1 obvious. The substituents disclosed in Quibell are used to prevent aggregation of the β -amyloid molecules themselves during synthesis. The sole purpose of the $N\alpha$ -substituents in the molecules of the Quibell is to prevent any association whatsoever with other identical molecules, so that they remain soluble and monomeric during synthesis.

In contrast, the embodiment of the present invention as claimed include a first edge that associates with a target β -strand formed by a separate peptide containing molecule. The molecules disclosed in Quibell would not be capable of such association because the AcHmb substituent groups are positioned on both sides of the β -amyloid. This is shown at the top of page 2020, where the groups are substituted on both odd and even amino acid residues, resulting in them lying along both edges of the β -amyloid molecule. Thus, the molecules are specially designed so that they cannot associate with any other peptide containing molecule. This clearly teaches away from the embodiment of the present invention as defined in Claim 1, in which the $N\alpha$ -substitutents lie along only the said second edge (i.e., only one edge of the β -strand forming section of peptide).

In addition, following the prevention of aggregation during synthesis, all of the AcHmb $N\alpha$ -substitutes are removed, as disclosed in the Quibell. This also teaches away from the embodiment of the present invention in which the $N\alpha$ -substitutes remains following association, in order to prevent further aggregation of naturally occurring β -amyloids.

Furthermore, the present invention relates to the formation of synthetic compounds designed to prevent aggregation of naturally occurring β -amyloids. These compounds are capable of acting as therapeutic compounds because of their small size and high specificity. Quibell teaches substituting large, naturally occurring β -amyloids to prevent self-aggregation during synthesis. The substituted compounds are not intended for any therapeutic used and would not therefore be considered relevant to the present invention at the time of filing.

Reply to Office Action of March 26, 2004

Finally, Applicant respectfully enclosed herewith the copy of Section 33.35 of the PCT Handbook, which states that PCT Contracting States have agreed to follow the unity of invention practice under the PCT. Since no unity of invention objection was raised by the ISA or IPEA with regards to the present invention, Applicant respectfully submits that a designated office "ought not" to raised a lack of unity objection (PCT Handbook Rel 6 (2000), Sec. 33.35).

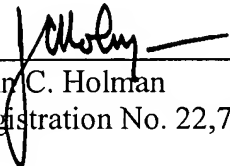
In light of the above comments, Applicant respectfully submits that the compounds covered by Claim 1 of the present invention are not obvious over Quibell. Therefore, Groups I to IV are linked by a special technical feature and the restriction requirement is improper.

An action on the merits of all of the claims and a Notice of Allowance thereof are respectfully requested.

Respectfully submitted,

JACOBSON HOLMAN PLLC

Date: May 13, 2004
(202) 638-6666
400 Seventh Street, N.W.
Washington, D.C. 20004
JCH/jc
Atty. Dkt. No.: P67518US0

By 
John C. Holman
Registration No. 22,769

Enclosure:

Copy of PCT Handbook Rel 6 (2000), Sec. 33.35

BEST AVAILABLE COPY

that time or because they were not part of the prescribed minimum documentation. The national laws on patentability, that is to say, on novelty, inventive step and industrial applicability or the equivalent thereto will usually differ to a greater or lesser extent from the corresponding criteria for the international preliminary examination (Article 27(5) PCT). For this reason, the international preliminary examination report is not binding on elected Offices (Article 33(1) and (5) PCT).

It is the practice of many designated Offices to require the applicant in a national application to supply details of prosecution of corresponding applications in other countries, especially when priority is claimed. In the case of an international application, this practice is restricted in that one elected Office cannot require the applicant to supply particulars of prosecution of the same international application before any other elected Office (Article 42 PCT).

One of the matters which may be raised in the national phase is whether the claims are directed to more than one invention. This is discussed at paragraph 33.35.

The grant or refusal of a patent or other kind of protection on an international application is the prerogative of the designated Offices in accordance with their national laws (Articles 11(3) and 27(5) PCT). The decisions on such matters by the designated Offices are open to appeal to higher authorities in exactly the same way as decisions on national applications are open to appeal (as to which see para. 33.48).

33.35 Unity of invention in the national phase

One of the matters which may be considered by designated Offices in the national phase is whether the claims are directed to more than one invention. If a designated or elected Office considers that a finding by the International Searching or Preliminary Examining Authority that there is a lack of unity of invention is justified and the applicant did not pay the additional search or examination fee in response to the Searching or Examining Authority's invitation, the unsearched or unexamined claims may be considered withdrawn unless the applicant pays a special fee to the designated or elected Office (Articles 17(3)(b) and 34(3)(c) PCT). This could presumably, national law permitting, give the applicant the opportunity to pursue the unsearched or unexamined claims before the designated Office, instead of the searched or examined claims or to have a national search or examination conducted against the claims unsearched or unexamined in the international phase prior to deciding whether to file a divisional application at the designated Office.

The PCT Contracting States have agreed to follow the practice under the Patent Cooperation Treaty on unity of invention (as to which see para. 23.9). Therefore, a designated Office ought not to raise an objection as to a lack of unity when the International Searching and/or Preliminary Examining Authority has found that the claims comply with the requirement for unity of

BEST AVAILABLE COPY

invention (Rule 13 PCT). When the issue of unity of invention has been raised in the international phase and a protest against an invitation to pay additional search or examination fees has been upheld (paras 29.13 and 34.34 respectively), the applicant can ask the International Searching or Preliminary Examining Authority, as the case may be, for copies of the decision on the protest to be supplied to the designated Offices. A translation of such decision should accompany any prescribed translation of the international application itself (paras 33.7 and 33.16).

33.36 Non-prejudicial disclosures

Many national laws contain provisions for excluding certain disclosures of an invention before the filing date or before the priority date of a national patent application from consideration when deciding whether that invention as claimed in the national application meets the criteria for patentability, having regard to the prior art. Such disclosures are usually called "non-prejudicial disclosures" or "exceptions to lack of novelty". Depending on the national law, a non-prejudicial disclosure might be a disclosure without the consent of the applicant (a wrongful disclosure or an "evident abuse"), a disclosure of the invention at an exhibition, especially an international exhibition within the terms of the 1928 Convention on International Exhibitions, as amended, or a disclosure of the invention by or with the consent of the inventor or the applicant within a grace period. Such non-prejudicial disclosures are mentioned in the 1963 Strasbourg Convention on Unification, Articles 4(4) and 12(1)(b) (Appendix VIII of this Handbook). Provisions concerning disclosures at official or officially recognized international exhibitions are also contained in the Paris Convention, Article 11 (Appendix VII). Some national laws require that particulars of the circumstances of a disclosure be filed with the patent application in order that the disclosure shall be non-prejudicial.

The Patent Cooperation Treaty itself does not contain any provisions as to non-prejudicial disclosures but Rule 4.17(v) PCT provides a mechanism for furnishing particulars of non-prejudicial disclosures or exceptions to lack of novelty in the international phase in order to comply with requirements of national laws applicable in designated States. If a declaration as to non-prejudicial disclosures or exceptions to lack of novelty, using the standardized wording prescribed in Section 215 of the PCT Administrative Instructions, is appropriate for the designated Offices identified therein, such a declaration may have been included in the request at the time of filing, as described in paragraph 21.10A, in order that the particulars as to the non-prejudicial disclosures shall have been furnished at the time of filing of the international application. Alternatively, such a standardized declaration as to non-prejudicial disclosures, etc., may have been furnished later in the international phase, as described in paragraph 27.12B, although the later furnishing of particulars as to a non-prejudicial disclosure may not meet the requirements of the national laws applicable at some designated Offices. There is also the possibility of particulars of